REMARKS

Claims 17-23 were pending in the present application. Claims 17, 18 and 20 have been amended as discussed during the interview to more specifically define the hearing loss sequences on the microarray to be those that relate to genetic sequences found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes. New Claims 25-37 have been added. Support for the amendments to the claims and newly added claims can be found throughout the specification as originally filed. More particularly, support for the amendments to Claims 17, 18 and 20 and new Claims 25-37 can be found at, for example, paragraphs [0017]-[0018], [0021]-[0022], [0024] and [0035] of the published application. Entry of the amendments and new claims and reconsideration is respectfully requested.

Claims 17-23 and 25-37 are pending and presented for further examination. Applicants respectfully submit that for the reasons set forth hereinbelow, pursuant to the interview, and in light of the Interview Summary and amendments, the pending claims are in condition for allowance.

Rejections Under 35 U.S.C. §103

Claims 17 and 22-23

Claims 17 and 22-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Morton *et al.* (*Human Molecular Genetics*, 2002 Vol. 11 p. 1229) in view of Choo *et al.* (*The Journal of Pediatrics*, February 2002, p. 148). The Examiner states that Morton *et al.* disclose genetic mutations found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A, but fails to teach a microarray comprising these genetic mutations. According to the Examiner, Choo *et al.* disclose that a "deafness gene chip" could be developed to screen newborns for gene mutations that cause or predispose that infant to significant hearing impairment. The Examiner concludes that an ordinary artisan would be motivated to place the known gene mutations as taught by Morton *et al.* onto an array as taught by Choo *et al.* to screen patients with a large number of gene mutations quickly and efficiently. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Pursuant to the interview, Applicants have amended independent Claim 17 to clarify that the set of diagnostic hearing loss sequences on the microarray "consists essentially of genetic sequences found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes." As such, the

diagnostic hearing loss sequences on the microarray are more specifically defined to be those that relate to genetic sequences found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes.

The list of hearing loss mutations in Morton *et al.* provides no prioritization to the importance or prevalence of these mutations or genes in a population. One of ordinary skill in the art would not know, based on the generic list of genes provided in Morton *et al.*, to pick the specific genetic sequences as recited in amended Claim 17. Choo *et al.* is silent as to any specific hearing loss gene, mutation or SNP. Thus, one of skill in the art would not know, based on the cited references, to pick genetic sequences specifically found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes. As discussed in Applicants' response filed on December 7, 2007, Applicants have provided evidence of unexpected results from the specifically recited genetic sequences. *See also*, Declaration of John H. Greinwald, Jr., M.D., FAAP with accompanying references, submitted on December 7, 2007.

Applicants submit the evidence of record including unexpected results and long-felt need is strong evidence of the nonobviousness of the claimed microarrays. As discussed in Applicants' previous response, according to Dr. Greinwald, the procedures used for hearing loss diagnosis to date provide little or no diagnostic or prognostic information (Greinwald Declaration, ¶8). Beyond GJB2, it was uncertain what genetic mutations are next most prevalent in patients with hearing loss (Greinwald Declaration, ¶7). Also, key genes commonly found mutated in SNHL, aside from GJB2, were previously unidentified. (Greinwald Declaration, ¶¶9-10). Microarrays comprising genetic sequences found in CDH23, MYO7A and OTOF, SLC26A4 and USH2A satisfy the long-felt need for a tool for the accurate, simple, efficient and highly cost-efficient diagnosis of hearing loss. (Greinwald Declaration, para. 11). In addition, such microarrays satisfy a need for tools for providing diagnostic and/or prognostic information on hearing loss. Applicants submit that even if the Examiner maintains that a *prima facie* case of obviousness has been established, these secondary considerations necessitate a finding of nonobviousness.

Applicants respectfully note that, during the interview, the Examiner's supervisor indicated that the recitation of the transitional phrase "consist essentially of" would result in a new matter rejection if not defined in the specification as filed. However, the transitional phrase "consist essentially of" is a phrase which is well-known in the art to limit the scope of a claim to the specified materials "and those that do not materially affect the basic and novel

characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). *See*, M.P.E.P. § 2111.03. As discussed above, the basic and novel characteristic of the claimed microarrays is the selection of hearing loss sequences specifically found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes. Applicants' disclosure provides ample support for microarrays including specific genetic sequences and materials that do not materially affect the basic and novel characteristics of the claimed microarrays. As such, the amendment to Claim 17 does not constitute new matter.

For at least the reasons stated above, pursuant to the interview, and in light of the Interview Summary, Applicants believe that the amendments to the claims overcome the obviousness rejection. Withdrawal of the obviousness rejection is respectfully requested.

Claims 18-21

Claims 18-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Morton *et al.* in view of Choo *et al.*, and in view of Weston *et al.* (*American Journal Human Genetics* 1996 Vol. 59, p. 1074) and Guo *et al.*, (2002, *Genome Res.*, Vol. 12: 447-457). The Examiner found that it would have been obvious to detect any of the mutations of MYO7A in a single exon an adjacent exon, because Weston *et al.* disclose various mutations of MYO7A which are in a single exon, and are found in a combination of adjacent exons. Applicants note that although the Examiner has cited Guo *et al.* in the rejection, there is no discussion of the Guo *et al.* reference in the Office Action. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

As noted above, Applicants have amended independent Claim 17 to clarify that the set of diagnostic hearing loss sequences on the microarray "consists essentially of genetic sequences found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes." Thus, the diagnostic hearing loss sequences on the microarray are more specifically defined to be those that relate to genetic sequences found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes.

As discussed above, the evidence of record including unexpected results and long-felt need is strong evidence of the nonobviousness of the claimed microarrays. The Weston *et al.* reference relates only to MYO7A, and does not disclose genetic sequences found in CDH23,

OTOF, SLC26A4 and USH2A genes. Therefore, the Weston *et al.* reference does not supplement the deficiencies of Morton *et al.* and Choo *et al.*

For at least the reasons stated above, pursuant to the interview, and in light of the Interview Summary, Applicants believe that the amendments to the claims overcome the obviousness rejection. Withdrawal of the obviousness rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 7-25-2008

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